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Remarks

Drawings

The Examiner appears to misunderstand the figures as depicting the prior art. All of the figures represent the coils provided with the coating of the invention and the effect which the invention has in tissue. While the underlying coils are GDC coils and were previously known, the coating which is disposed on them as shown in the photographs is not. Hence, it would entirely inappropriate to characterize any of the figures as merely depicting the prior art. The figures in each case depict the claimed invention.

Claim Rejections - 35 USC§ 112

Claim 30 has been responsively amended to provide antecedent basis for "coils."

Claim Rejections - 35 USC§ 102

Claims 1 - 5, 7 - 8, 11 - 16, 18 - 19, and 22 - 33 were rejected as being anticipated by **Roth et al.** US Patent No. 5,879,713.

Regarding claim 1, the Examiner cited **Roth** as disclosing an endovascular apparatus for developing an inflammatory response in a body cavity with cellular manipulation having: A separable implant (such as a coating on a tubular biological structure (whether natural or artificially formed), as recited in column 13, lines 5-15, a microparticle, etc.) made at least in part of at least

one biocompatible and bioabsorbable polymer, as recited in column 3, lines 30-67 and columns 4-6; An endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity (such as those inherent for placement of stents as well as that recited in column 11, lines 4-12 and columns 13 and 14 for delivery of microparticles).

Roth is directed to a specific delivery means for nucleic acid molecules and other drugs, or bioactive molecules (col. 2, line 38 et.seq.). It is important to note the **Roth's** teaching is that:

> "The polymeric carrier can be administered directly, for example, by spraying or application of a solution, or indirectly, through a catheter, endoscope, or laparoscope. **When delivered to the interior of a hollow organ, the process of application must not cause collateral injury by prolonged blockage of flow through the organ.**" (col. 11, lines 1 – 3, emphasis added)

Thus, in the very next lines when **Roth** teaches that the delivery means administers microparticles and percutaneous applications of the drug to the interior of hollow organs or natural body cavities of a polymeric coating, film, gel, or stent by providing a polymer coating or layer on the surface of tissues using catheters, laparoscopes, and endoscopes (col. 11, lines 5 et.seq.), it must be understood in context that **Roth** requires that ***the process of application must not cause prolonged blockage of flow through the organ.*** This is exactly the opposite of what the applicant seeks, namely permanent occlusion of the aneurysm to all flow by inducing the growth of scar tissue to seal over the body cavity or aneurysm. It cannot be logically maintained that **Roth** both explicitly discloses an apparatus and method for not blocking flow in a body cavity and at

the same time by such disclosure inherently discloses an apparatus and method for blocking flow in a body cavity. Quite the opposite is the case. **Roth** inherently and explicitly discloses only an apparatus and method for not blocking flow in a body cavity.

Roth does not mention again anywhere in the specification the administration of a stent or provide any disclosure regarding the nature of the stent. **Roth** teaches not to block the flow in the body cavity. It cannot also be maintained that it thus discloses that flow in the body cavity is blocked by the polymer administration.

There is no mention whatsoever in **Roth** of inducing the formation of scar tissue in the body cavity as required by the amended claim.

Claim 1 as amended calls for the polymer to cause permanent blockage of flow of blood in the body cavity by inducing the formation of scar tissue therein.

Roth requires at col. 3, lines 30 – 34, that:

> "Polymeric carriers must be biodegradable, sufficiently porous to permit efflux of the biologically active molecules, and **sufficiently non-inflammatory** and biocompatible **so that inflammatory responses do not prevent the delivery of the biologically active molecules to the tissue**." (emphasis added)

In contrast, claim 1 is expressly directed to "an endovascular apparatus for developing an inflammatory response in a body cavity". Again, **Roth** discloses the use of noninflammatory polymers. **Roth** does not disclose the use of purposively inflammatory polymers.

Regarding claim 7, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer in which at least one protein is

selected from the group consisting of poly~glycolic acid/poly-L-lactic acid copolymers, polycaprolactive, polyhydroxybutyrate/hydroxyvalerate copolymers, poly-L-lactide, and polydioxanone.

Roth does not disclose the use of any of these proteins as set forth in amended claim 7.

Regarding claim 8, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable protein that is at least one protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, laminin, and gelatin, as recited in column 3, lines 61-67.

Roth only discloses gelatin and does not disclose fibrinogen, fibronectin, vitronectin, or laminin as required by amended claim 8.

Regarding claim 11, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing, as recited in column 3, lines 30-40 for example. However, column 3, lines 30-40, states:

> "Polymeric carriers must be biodegradable, sufficiently porous to permit efflux of the biologically active molecules, and sufficiently non-inflammatory and biocompatible so that inflammatory responses do not prevent the delivery of the biologically active molecules to the tissue. It is advantageous if the carrier also provides at least partial protection of the biologically active molecules from adverse effects of proteases and nucleases. In addition, it is advantageous if controlled, sustained delivery can be obtained using the polymeric carriers."

There is nothing in this teaching disclosing a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing.

Regarding the method claims 12 - 16 and 18 - 19, the Examiner contends that the disclosures of **Roth** cited in response to apparatus claims 1 – 11 anticipate the method claims as well.

Claims 12 - 16 and 18 – 19 are strongly distinguished from **Roth** in that **Roth** as noted above discloses the exact opposite method from that claimed in each instance by the applicant. The point is that Roth cannot be cited as simultaneously enabling a first method and *subsilencio* a second opposite method. Claim 12 as amended providing a separable implant having a form and comprised at least in part of at least one biocompatible and bioabsorbable polymer to cause permanent blockage of flow of blood in the body cavity by inducing the formation of scar tissue therein.

A stent does not have a form which causes permanent blockage of flow of blood in the body cavity. Its form is such that there is no blockage of flow of blood in the body cavity.

Roth again discloses polymers which **do not** blockage of flow of blood in the body cavity, and **Roth** discloses nothing about inducing the formation of scar tissue in the body cavity. Thus, it cannot be maintained that **Roth** discloses each and every element of the claim. Claims 13 – 19 are directed methods of using certain materials in ways and for effects which are not disclosed in **Roth**, and hence are not disclosed in the claimed sense of the method in **Roth**.

Regarding claim 25, The Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that has a selected composition to provide a controlled degradation time to thereby control intravascular

inflammatory reactions, as recited in column 13.

There is no disclosure in column 13 regarding anything about intravascular inflammatory reactions or for that matter about a controlled degradation time of the polymer. While elsewhere in **Roth** there are references on occasion to degradation of the polymer, it is never in the context of control of intravascular inflammatory reactions. Hence the claimed polymers are not the same.

Regarding claim 26, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that regenerates tissue through the interaction of immunologic cells or inherently discloses the same.

The applicants respectfully disagree that there is any disclosure at all in **Roth** directed to a polymer that regenerates tissue through the interaction of immunologic cells. Hence the claimed polymers are not the same. The regeneration which is disclosed in Roth is in reference to growth factors and not by interaction of immunologic cells (col. 14, lines 62 – 65).

Regarding claim 27, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis, although the Examiner admits that **Roth** does not explicitly so disclose but given that disclosed would accomplish that claimed.

The applicants respectfully disagree that there is any disclosure at all in **Roth** directed to a polymer that polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis. The degradation

of the disclosed polymers in **Roth** is never linked in any way to acceleration of fibrosis. Hence the claimed polymers are not the same.

Regarding claim 28, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that accelerates fibrosis within an aneurysm to more strongly anchor the implant than does metal coils, as recited in column 14, lines 5-25.

Column 14, lines 5-25, discloses the use of a paving layer in several contexts. There is no disclosure of a coil or any other implant body other than a paving layer. There is no disclosure of fibrosis. Hence the claimed polymers are not the same.

Regarding claim 29, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more resistant to a water hammer effect of pulsatile blood than when treated by metal coils.

The applicants respectfully disagree in that **Roth** never discloses anything about a polymer which is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more resistant to a water hammer effect of pulsatile blood than when treated by metal coils. Hence the claimed polymers are not the same.

Regarding claim 30, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that restricts coil compaction by accelerated scar formation.

The applicants respectfully disagree in that **Roth** never discloses anything about a polymer which restricts coil compaction by accelerated scar formation. Hence the claimed polymers are not the same.

Regarding claim 31, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that restricts aneurysm recanalization by accelerated scar formation while admitted that no such disclosure is ever explicitly made.

The applicants respectfully disagree in that **Roth** never discloses anything about a polymer that restricts aneurysm recanalization by accelerated scar formation. Hence the claimed polymers are not the same.

Regarding claim 32, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that induces organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves while admitting that there is no explicit disclosure to this effect.

The applicants respectfully disagree in that **Roth** never discloses anything about a polymer that induces organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves. Hence the claimed polymers are not the same.

Regarding claim 33, the Examiner contends that **Roth** discloses a biocompatible and bioabsorbable polymer that is less thrombogenic than metal

coils and accelerates aneurysm healing with less thrombogenicity.

The applicants respectfully disagree in that **Roth** never discloses anything about a polymer that is less thrombogenic than metal coils and accelerates aneurysm healing with less thrombogenicity. Hence the claimed polymers are not the same.

The characteristics attributed to the polymers defines the polymers and serve to distinguish them from polymers which do not have such characteristics.

Claims Rejections – 35 USC 103(a)

Claim 34 was rejected as being obvious over **Roth**. The Examiner contended that it would be obvious to provide mixture of the vascular endothelial growth factor and a basic fibroblast growth factor for the purpose of promoting proper healing. The Examiner noted that the specification for the current application does not provide any criticality to the mixture, rather just states that it is preferred.

The applicants respectfully maintain that patentability does not require criticality to be nonobvious over the art. A preferred embodiment may be patentable as well.

The Examiner contended that a biocompatible and bioabsorbable polymer that is a mixture of polyglycolic/poly-L-lactic acid copolymers with a 90/10 molar ratio of glycolic to L-lactic acid would also be obvious. The specification for the current application does not demonstrate the criticality, rather states that it is in one embodiment.

There is no suggestion or motivation in Roth that any particular molar ratio of glycolic to L-lactic acid is to be sought for any purposes, let alone the degree of control of the inflammatory response as set forth in the amended claim.

Claims 35 - 39 were rejected as being obvious over **Roth** in view of **Boock et al.** in US Patent No.6, 187,024. **Boock** has a priority date of Nov. 10, 1998. The present application claims back to a priority date of Jan. 27, 1998 through a copending provisional application. Thus, **Boock** is not piror art against the present invention. The present invention is licensed to Target Therapeutics, the assignee of **Boock,** who derived their subject matter from the teachings of applicants as set out in the claimed provisional.

Double Patenting

Claims 1 - 39 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,423,085.

The applicant submits herewith a terminal disclaimer.

The applicant respectfully requests advancement of the claims to issuance.

Respectfully submitted,

Daniel L. Dawes
Reg. No. 27123
949 223 9600
fax 949 223 9610

Mailing Address:
Daniel L. Dawes
5252 Kenilworth Dr.
Huntington Beach, California 92649